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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,968	07/28/2003	Michael Porat	03128CIP	4080

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EXAMINER	
BETTON, TIMOTHY E	
ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,968	PORAT, MICHAEL	
	Examiner	Art Unit	
	TIMOTHY E. BETTON	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Request for Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8 July 2008 has been entered.

Status of the claims

Applicants have cancelled the claims of record 1-15 and have newly added claims 16-30 which include no new matter.

Claims 16-30 are drawn to a method for providing for safe sexual relations and reducing HIV transmission. Secondly, the claims are drawn to a composition, wherein the antiseptic is chlorhexidine or a salt thereof. These newly added claim disclose identical subject matter as disclosed in cancelled claims 1-15.

The claims as presented in current set disclose an issue that reads broadly on the method for providing for safe sexual relations in a target population in need thereof to practice safe sexual relations. However, in the alternative, the claim could be drawn to a target population in need thereof in order to practice safe sexual relations because this particular target population is infected with an STD or HIV.

Specifically, applicants claim a broad genus of human subjects that would be in need thereof because of the general reasoning of practicing safe sexual practices. Within this genus are a subgenus drawn to human subjects that would be in need thereof based on this population

being infected and further being in need thereof in order to prevent spreading the disease to uninfected human subjects.

Status of the Rejection

As cited in previous action: Both said references are directed toward contraceptive products via disclosure and use of components such as a spermicide, an antiseptic, and a fungicide in specific percent (mg/100ml) dosage ranges. Chantler et al. relies on Cooper et al. for motivation to incorporate together based on the disclosure of antiseptic agents in Cooper et al. and embodiments of dosing concentration amounts and ranges. The Cooper et al. reference is replete with embodiments drawn to specific concentrations and dosage ranges which makes the claimed obvious of claimed invention. Additionally, Cooper et al. further provides motivation for Chantler et al via the specific disclosure of chlorhexidine in Chantler et al. Based upon the fact that Cooper et al. clearly teaches contraceptive jellies, and Chantler et al. teaches chlorhexidine as an effective contraceptive, one of ordinary skill in the art would be motivated to use the two together because they are both known for the same purpose.

Thus, claims 16-30 remain rejected under the 35 U.S.C. 103(a) rejection which are written generally in the same format as the claims which were issued in the parent application serial number 07/978671, now USPN 6,624,198. Accordingly, rejections are maintained for the reasons of record set forth at pages 5-11 (principally page 6, paragraph in italics) of the previous Office Action dated 7 May 2008.

Applicant's Request to Withdraw Obviousness-Type Nonstatutory Double-Patenting

Page 4 of the Remarks filed 7 June 2007 discloses: Claims 1-12 and 14 have been rejected under the judicially created doctrine of obviousness-type double-patenting over claims 1 and 9 of US 6624198. Applicant recognizes the applicability of the double patenting rejection, and will file a terminal disclaimer to remove this rejection at such time as the disputed claims are found to be allowable.

However, there is no indication of a Terminal Disclaimer filed. Therefore, the Obviousness-Type Nonstatutory Double-Patenting rejection is maintained.

In response to the maintained Obviousness-Type Nonstatutory Double-Patenting rejection, applicant have cancelled claims 1-15.

Newly added claims 16-30 are now rejected over claims 1 and 9 of US 6624198.

Obviousness-Type Nonstatutory Double-Patenting (Maintained)

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887,225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or

agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 9 of U.S. Patent No. 6624198 (Porat). Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and Porat (USPN 6624198) claim a prophylactic lubricating/spermicidal composition for its use in sexual relations, including prevention of infection by HIV and other viruses.

The claimed invention of the instant application and the referenced patent 6624198 in that said patent disclose same composition with similar methods of use. Thus, it would be obvious to one of ordinary skill in the art at the time the invention was made to select a species of the genus, observe similar properties and therapeutic effects and therefore use (as in a method for use).

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al (USPN 4,242,359) and Chantler et al. (USPN 4,602,042).

Cooper et al teach a method for treating mammalian spermatozoa with amphipathic amines in order to induce loss of fertility and/or head-tail cleavage of the sperms under mild

physiological conditions. In the presence of primary alkyl or cycloalkyl amines containing between 4 to 7 carbon atoms at concentrations of about 15 .lambda./ml, sperms are rapidly dissociated into heads and tails under physiological pH- and temperature-conditions. Further disclosed are topical contraceptive compositions containing amphipathic amines (abstract only).

Cooper et al. teach a cyclohexylamine containing composition. An aqueous solution of cyclohexylamine hydrochloride is incorporated into a hydroxyethylcellulose gel (commercial product K-Y Jelly) to form gel compositions containing 5-10% (w/w) of cyclohexylamine hydrochloride (column 7, lines 24-29).

Additionally, Cooper et al. teach the topical contraceptive composition may comprise supplementary topical antiseptic and germicidal agents, which are conventionally used in topical contraceptive compositions in addition to the amphipathic amine. Suitable supplementary contraceptive agents are, e.g., physiologically acceptable mono (alkylphenyl) ethers of polyethylene glycols wherein the alkyl group preferably contains between 1 and 10 carbon atoms and the polyethylene glycol preferably contains 2 to 12 ethyleneoxy units, such as **nonoxynol 9**, a p-nonylphenyl ether of a polyethylene glycol, mono (isooctylphenyl) ether of polyethylene glycol, mono (p-diisobutylphenyl) ether of polyethylene glycol and the like, or physiologically acceptable benzyldimethylalkylphenoxyethoxyethyl ammonium salts wherein the alkyl groups preferably contain 1 to 10 carbon atoms, or benzyldimethylalkyl ammonium salts wherein the alkyl groups preferably contain 8 to 18 carbon atoms, such as methylbenzethonium or benzethonium salts, e.g., chlorides, or benzalkonium chloride (column 8, lines 66-68 and column 9, lines 1-17).

Accordingly, Cooper et al. teach suitable jelly-formulations comprising gels containing a cellulose-derivative such as hydroxyethylcellulose, and optionally adjuvants such as thickening agents, e.g., soluble starch, and moistening agents, e.g., propylene glycol, into which an amount of between about 5 to about 10% by weight of an acid-addition salt of the amine is incorporated (column 9, lines 36-42). Thus, Cooper et al. teach HEC for use in the disclosed contraceptive jelly formulations.

Further, Cooper et al. teach a non-toxic topical contraceptive composition, which exhibit a high contraceptive activity without being irritating to the **vaginal mucosa** (column 1, lines 55-58).

Still further, Cooper et al. teach a topical contraceptive formulation according to the present invention, which are water soluble with specific pH ranges, [i.e.]; the active ingredients are incorporated into **water-soluble or water-dispersible** conventional pharmaceutical carriers. […]. Other gel-forming and thickening agents are vegetable gums, which **are stable at pH values between 4 and 9**, preferably tragacanth or acacia, or physiologically acceptable synthetic thickening agents like polyvinyl **alcohols**, etc. (column 9, lines 18-35).

Cooper et al. cites percentages or mg/ 100 ml of contraceptive jellies in Example 2, where all the active ingredients according to instant claim 14 are in increased dose ranges, with the exception of methyl cellulose in comparison to HEC of instant invention. The methyl paraben component of instant invention is encompassed by the cited dosage ranges for methylparaben by Cooper et al.

Cooper et al. teach 15 lambda of a composition as disclosed in one ml of the buffered mixture containing 10sup7 spermatazoa, causes 93-99% of the spermatozoa to dissociate (column 6, lines 20-27).

Cooper et al. teach good results are normally attained via the composition in aqueous reaction media containing 1 and about 500 and 5 and about 500, respectively (column 6, lines 53-62).

Further, Cooper teach an amine concentration that prevents sperm motility at between 3-4% and 1-5%, respectively (column 7, lines 15-18).

Accordingly, Cooper et al. teach an amount of amphipathic amine at preferable concentrations as disclosed:

The topical contraceptive compositions contain a non-toxic amount of the above-described amphipathic amines per dosage unit which is effective to prevent the entry of any fertilizing sperms into the female cervix, but which is non-irritating to the vaginal mucosa. The concentration of the amphipathic amine within the contraceptive composition may vary considerably depending on which amine is used, as well as on the chemical and physical properties of the other ingredients of the composition. Usually, the amount of amphipathic amine is between about 0.1 and about 50%, preferably between about 0.5 and about 50%, especially between about 1 and about 25% in semi-solid compositions and between about 0.1 and about 15%, especially between about 0.2 and about 10% in solid compositions (column 8, lines 51-65).

Furthermore, Cooper et al teach additional adjuvants, which may be incorporated into these formulations, such as, **antiseptic agents** (column 9, line 61).

Chantler et al. teach contraceptive products specifically comprising chlorhexidine (column 2, line 45; column 4, lines 52 and 53).

Thus, it would have been *prima facie* obvious to the skilled artisan at the time of invention to at once recognize with a reasonable expectation of success, the combining of and/or the incorporating together of the teachings of Cooper et al. and Chantler et al. Cooper and Chantler et al. teach the central objective of instant claimed invention which are both drawn to contraceptive products.

Both said references are directed toward contraceptive products via disclosure and use of components such as a spermicide, an antiseptic, and a fungicide in specific percent (mg/100ml) dosage ranges. Chantler et al. relies on Cooper et al. for motivation to incorporate together based on the disclosure of antiseptic agents in Cooper et al. and embodiments of dosing concentration amounts and ranges. The Cooper et al. reference is replete with embodiments drawn to specific concentrations and dosage ranges which makes the claimed obvious of claimed invention. Additionally, Cooper et al. further provides motivation for Chantler et al via the specific disclosure of chlorhexidine in Chantler et al. Based upon the fact that Cooper et al. clearly teaches contraceptive jellies, and Chantler et al. teaches chlorhexidine as an effective contraceptive, one of ordinary skill in the art would be motivated to use the two together because they are both known for the same purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shengjun Wang/
Primary Examiner, Art Unit 1617

TEB